



INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Oncology Services

LIBRARY REFERENCE NUMBER: PROMOD00061
PUBLISHED: APRIL 20, 2021
POLICIES AND PROCEDURES AS OF FEBRUARY 1, 2021
VERSION: 3.0

Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of November 1, 2018 Published: July 30, 2019	New document	FSSA and DXC
2.0	Policies and procedures as of February 1, 2020 Published: March 13, 2020	Scheduled update	FSSA and DXC
3.0	Policies and procedures as of February 1, 2021 Published: April 20, 2021	Scheduled update: <ul style="list-style-type: none"> • Removed outdated information • Added a reference to the DME module in the Introduction section • Added the CAR-T Treatments section: <ul style="list-style-type: none"> – Added the Axicabtagene ciloleucel (Yescarta) section – Added the Brexucabtagene autoleucel (Tecartus) section – Updated the Tisagenlecleucel (Kymriah) section • Removed the <i>Moxetumomab pasudotox-tdfk (Lumoxiti)</i> section 	FSSA and Gainwell

Table of Contents

Introduction.....	1
Chemotherapy and Radiation as Outpatient Hospital Services	1
Brachytherapy Services in the Outpatient Setting.....	1
Radioimmunotherapy.....	2
Physician-Administered Oncology Drugs.....	2
CAR-T Treatments	2
Axicabtagene Ciloleucel (Yescarta)	2
Brexucabtagene Autoleucel (Tecartus).....	3
Tisagenlecleucel (Kymriah).....	3
Cemiplimab-rwlc (Libtayo)	4
Copanlisib (Aliqopa).....	4
Durvalumab (Imfinzi)	4
Lutetium Lu 177 Dotatate (Lutathera)	5
Sipuleucel-T (Provenge).....	5
Trastuzumab-anns, Biosimilar (Kanjinti).....	5

Oncology Services

*Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system. For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect, or Hoosier Healthwise member services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the [IHCP Quick Reference Guide](#) available at in.gov/medicaid/providers.*

For updates to information in this module, see [IHCP Banner Pages and Bulletins](#) at in.gov/medicaid/providers.

Introduction

The Indiana Health Coverage Programs (IHCP) covers oncology services, including cancer prevention, diagnosis, therapeutic treatment, rehabilitation, and palliative care, as described in this module.

For information about screening and evaluation for cancer, see the [Genetic Testing](#), [Obstetrical and Gynecological Services](#), [Laboratory Services](#), and [Radiology Services](#) modules.

For information about bone marrow and stem cell transplants (including coverage and prior authorization requirements), see the [Surgical Services](#) module.

For information about devices used in the treatment of cancer, see the [Durable and Medical Equipment and Supplies](#) module.

Chemotherapy and Radiation as Outpatient Hospital Services

In accordance with *Indiana Administrative Code 405 IAC 5-28-10*, outpatient administration of chemotherapy and costs related to this therapy (including catheterization, physician visits, cost of drugs and solutions, pump regulators, and servicing) are covered and do not require prior authorization.

All outpatient hospital chemotherapy and radiation treatment services are billed on the institutional claim (UB-04 claim form, 837I electronic transaction, or IHCP Provider Healthcare Portal [Portal] institutional claim). When chemotherapy and radiation treatment services are rendered on the same day, all applicable components should be billed. See the [Outpatient Facility Services](#) module for more information.

Note: Prior authorization is required when chemotherapy services are provided by a home health agency. For more information about services provided by a home health agency, see the [Home Health Services](#) module.

Brachytherapy Services in the Outpatient Setting

The IHCP covers certain Healthcare Common Procedure Coding System (HCPCS) codes for brachytherapy services performed in an outpatient setting. These services are billed on an institutional outpatient claim, including outpatient crossover claims. These codes are **not** separately reimbursable on professional claims (CMS-1500 claim form, 837P electronic transaction, or Portal professional claim).

Information about code-specific coverage, revenue code linkages, prior authorization, and reimbursement is available on the Outpatient Fee Schedule, accessible from the [IHCP Fee Schedules](#) page at in.gov/medicaid/providers.

Radioimmunotherapy

Radioimmunotherapy is not a procedure typically performed more than once. Therefore, codes specific to the radioimmunotherapy procedure are limited to one unit per lifetime. The IHCP will reexamine the policy if future research determines that multiple dosing of the radioimmunotherapy regime is appropriate.

Providers should bill the diagnostic supply of ibritumomab tiuxetan (Zevalin) (A9542), the therapeutic supply of Zevalin (A9543), and the infusion and supply of rituximab (J9312) in the Zevalin regimen.

Physician-Administered Oncology Drugs

The following sections provide coverage and limitations for certain physician-administered drugs related to oncology. For general information about billing and reimbursement for physician-administered drugs, see the [Injections, Vaccines, and Other Physician-Administered Drugs](#) module.

*Note: Providers are reminded that all prior authorization requests for gene therapy must include a letter of medical necessity **and** supportive patient/clinical chart documents demonstrating member diagnosis requirements.*

CAR-T Treatments

The IHCP covers the chimeric antigen receptor T-cell (CAR-T) treatments with prior authorization as listed in this section.

Axicabtagene Ciloleucel (Yescarta)

The IHCP covers axicabtagene ciloleucel (Yescarta) with prior authorization. The member must meet the following prior authorization criteria:

- Has not previously received the Yescarta treatment
- Will be administered the Yescarta treatment:
 - At a Yescarta Risk Evaluation and Mitigation Strategy (REMS) Program-certified facility
 - By healthcare providers that have successfully completed the Yescarta REMS Program Knowledge Assessment
- Is at least 18 years of age
- After two or more lines of systemic therapy, has a diagnosis of relapsed or refractory large B-cell lymphoma, including any of the following:
 - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
 - Primary mediastinal large B-cell lymphoma
 - High-grade B-cell lymphoma
 - DLBCL arising from follicular lymphoma
- Does not have a diagnosis of primary central nervous system lymphoma

Yescarta is carved out of managed care and covered under the FFS medical benefit for all IHCP members. Claims for Yescarta cannot be processed through the pharmacy benefit. When provided in an inpatient setting, Yescarta is separately reimbursable from the inpatient DRG when billed as a professional claim.

Yescarta is billed using HCPCS code Q2041 – *Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.*

Brexucabtagene Autoleucel (Tecartus)

Effective for dates of services on or after January 1, 2021, the IHCP covers brexucabtagene autoleucel (Tecartus) with prior authorization. The member must meet the following prior authorization criteria:

- Has not previously received the Tecartus treatment
- Will be administered the Tecartus treatment:
 - At a Tecartus REMS Program-certified facility
 - By healthcare providers that have successfully completed the Tecartus REMS Program Knowledge Assessment
- Is at least 18 years of age
- Has a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Tecartus is carved out of managed care and covered under the FFS medical benefit for all IHCP members. Claims for Tecartus cannot be processed through the pharmacy benefit. When provided in an inpatient setting, Tecartus is separately reimbursable from the inpatient DRG when billed as a professional claim.

Tecartus is billed using HCPCS code C9073 – *Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose.*

Note: For dates of service on or after April 1, 2021, Tecartus is billed using HCPCS code Q2053 – Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Tisagenlecleucel (Kymriah)

The IHCP covers tisagenlecleucel (Kymriah) with prior authorization. Kymriah may be considered medically necessary when the member meets all the following criteria:

- Has not received prior tisagenlecleucel treatment
- Will be administered tisagenlecleucel treatment
 - At a Kymriah REMS Program-certified facility
 - By healthcare providers who have successfully completed the Kymriah REMS Program Knowledge Assessment
- Is either:
 - 25 years of age or younger with a diagnosis of B-cell lymphoblastic leukemia that is refractory or in second or later relapse
 - At least 18 years of age and:
 - Following at least two lines of systemic therapy, has a diagnosis of relapsed or refractory large B-cell lymphoma, including any of the following:
 - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
 - High-grade B-cell lymphoma
 - DLBCL arising from follicular lymphoma
 - Does not have a diagnosis of primary central nervous system lymphoma

Kymriah is carved out of managed care and covered under the FFS medical benefit for all IHCP members. Claims for Kymriah cannot be processed through the pharmacy benefit. When provided in an inpatient setting, Kymriah is separately reimbursable from the inpatient DRG when billed as a professional claim.

Kymriah is billed using HCPCS code Q2042 – *Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedure, per therapeutic dose.*

Cemiplimab-rwlc (Libtayo)

The IHCP covers cemiplimab-rwlc (Libtayo) with prior authorization. The member must be diagnosed with one of the following:

- Metastatic cutaneous squamous cell carcinoma (CSCC)
- Locally advanced CSCC and not a candidate for curative surgery or curative radiation

The prior authorization limit is 6 months.

Libtayo is billed using HCPCS code J9119 – *Injection, cemiplimab-rwlc, 1 mg*.

Copanlisib (Aliqopa)

The IHCP covers copanlisib (Aliqopa) therapy with prior authorization. Aliqopa therapy may be considered medically necessary when the member meets **all** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of follicular lymphoma
- Has relapsed, refractory, or progressive disease
- Has received at least two prior systemic therapies
- Will be using Aliqopa as monotherapy

Aliqopa therapy is not considered medically necessary for members who have experienced disease progression while on or following a PI3K inhibitor (for example, idelalisib, copanlisib).

This agent may be approved in 6-month durations or as determined through clinical review. The quantity limit is three 60 mg vials per 28 days. The recommended dose is 60 mg administered as a 1-hour intravenous infusion on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (3 weeks on and 1 week off), with continued treatment until disease progression or unacceptable toxicity.

Aliqopa is billed using HCPCS code J9057 – *Injection, copanlisib, 1 mg*.

Durvalumab (Imfinzi)

The IHCP covers durvalumab (Imfinzi) with prior authorization. Imfinzi may be considered medically necessary when the member meets **all** the following criteria:

- Is 18 years of age or older
- Has **one** of the following:
 - Locally advanced or metastatic urothelial carcinoma with **one** of the following:
 - Disease progression during or following platinum-containing chemotherapy
 - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
 - Non-small cell lung cancer (NSCLC) with **both** of the following:
 - Must be unresectable, stage III NSCLC
 - Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

Prior authorization is limited to 12 months. Authorization renewal, which is also limited to 12 months, requires the following criteria be met:

- Locally advanced or metastatic urothelial carcinoma
- No disease progression or unacceptable toxicities

Imfinzi is billed using HCPCS code J9173 – *Imfinzi (durvalumab)*.

Lutetium Lu 177 Dotatate (Lutathera)

The IHCP covers lutetium Lu 177 dotatate (Lutathera) with prior authorization. Lutathera therapy may be considered medically necessary when the member meets **all** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of unresectable, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumor (GEP-NET)
- Has somatostatin receptor-based imaging documenting somatostatin receptor-positive GEP-NET
- Has received long-acting somatostatin analog (SSA) therapy (that is, Somatuline Depot or Sandostatin LAR) for a duration of at least 12 weeks
- Has not received a prior course of therapy with Lutathera (that is, maximum of four doses at intervals of at least 8 weeks)

Lutathera therapy is not considered medically necessary for experimental/ investigational use for indications not supported by Centers for Medicare & Medicaid Services (CMS)-recognized compendia or acceptable peer-reviewed literature.

Lutathera is billed using HCPCS code A9513 – *Lutetium Lu 177, dotatate, therapeutic, 1 mCi*.

Sipuleucel-T (Provenge)

The IHCP covers sipuleucel-T (Provenge) with prior authorization. The following medical necessity criteria must be met:

- Diagnosis of metastatic castrate-resistant (hormone-refractory) prostate cancer
- Eastern Cooperative Oncology Group (ECOG) performance status 0–1
- Disease asymptomatic or minimally symptomatic
- Life expectancy greater than 6 months
- Serum testosterone level less than 50 ng/dL (17 nmol/L)
- No hepatic metastases

Provenge is billed using HCPCS code Q2043 – *Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF including leukapheresis and all other preparatory procedures, per infusion*.

Trastuzumab-anns, Biosimilar (Kanjinti)

The IHCP covers trastuzumab-anns, biosimilar (Kanjinti) with prior authorization. The member must be diagnosed with one of the following:

- HER2 overexpressing breast cancer
- HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

Kanjinti is billed using HCPCS code Q5117 – *Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg*.